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Supreme Court, U.S.
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No. 97-1018

IN THE
Supreme Court of the United States
OCTOBER TERM, 1997

BARBARA MITCHELL, *et al.*,
Petitioners,

v.

COLLAGEN CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

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BRIEF IN OPPOSITION

JOE W. REDDEN, JR.
Counsel of Record
KEITH A. JONES
BECK, REDDEN & SECREST
1221 McKinney Street
Suite 4500
Houston, TX 77010-2010
(713) 951-3700
Attorneys for Respondent

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts state common law requirements relating to safety or effectiveness that are in addition to or different from the federal requirements imposed in connection with granting premarket approval of a medical device pursuant to 21 U.S.C. § 360e(c).*

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* Respondent Collagen Corporation has no parent company and no nonwholly owned subsidiaries.

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BRIEF IN OPPOSITION

STATEMENT OF THE CASE

1. Company history and regulatory background.

In the early 1970s, a group of biochemists and physicians at Stanford University developed a purified form of bovine collagen, a natural protein that provides structural support for skin, muscles, tendons, and bones. Together with other investors, they organized respondent Collagen Corporation ("Collagen") to manufacture and distribute collagen products to be used in various medical treatments. The principal product at issue in this case, Zyderm® Collagen Implant ("Zyderm"), is injected under the skin to correct or improve soft tissue deficiencies that arise from disease, trauma, or aging.

Zyderm is classified by the Food and Drug Administration ("FDA") as a Class III medical device subject to

regulation under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c-360*l*. With two exceptions not germane to Zyderm, a new class III medical device may not be introduced to the market until the FDA has determined that it satisfies stringent requirements relating to safety and effectiveness.

The process by which the FDA makes this determination, "known as the 'premarket approval,' or 'PMA' process, is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2246-47 (1996). Pursuant to this PMA process, the FDA closely scrutinizes the ingredients, components, manufacturing methods, and labeling to be used in conjunction with the device. *See* 21 U.S.C. § 360e(c), (d); 21 C.F.R. Part 814.

The FDA's approval of a device for marketing pursuant to the PMA process "constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards, and labeling. The FDA's determination is specific to the product." Pet. App. 21a. Once the device has been approved for marketing, the manufacturer is required by the FDA to adhere to the standards established during the PMA process and may not make any changes relating to safety or effectiveness without the FDA's prior approval. *Id.* at 16a-17a. The PMA process thus imposes specific requirements directly related to the safety and effectiveness of the particular device. *Id.*

Collagen invoked this rigorous PMA process by filing an application with the FDA for premarket approval of Zyderm in 1980. Following more than a full year of detailed investigation, the FDA determined that Zyderm satisfied all requirements relating to safety and effectiveness and approved it for marketing. 46 Fed. Reg. 46394 (1981). "During 1991-92, the FDA conducted a reexamination of Zyderm and concluded that its decision to approve Zyderm"s PMA was appropriate." Pet. App. 3a.

2. Facts and proceedings in this case.

a. In 1988 petitioner Barbara Mitchell received a series of injections of Zyderm as treatment for facial wrinkles. She asserts that subsequent to her treatments she developed an autoimmune disease and that she believes Zyderm caused this disease. In 1993 she and her husband sued Collagen in Indiana state court, alleging negligence, strict liability, mislabeling and adulteration, fraud, and breach of warranty. Collagen removed the case to the United States District Court for the Northern District of Indiana, where jurisdiction rested on 28 U.S.C. § 1332.

The district court granted summary judgment for Collagen on the ground that petitioners" tort claims were precluded by 21 U.S.C. § 360k(a), the MDA preemption statute. That statute bars the states from subjecting a medical device to "any requirement—(1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." The district court determined (1) that state tort law imposes "requirements'" within the meaning of this statute and (2) that enforcement of the particular tort laws invoked by petitioners would result in the imposition of state requirements different from or in addition to the federal requirements applicable to and satisfied by Zyderm under the MDA. Pet. App. 27a-52a. The court further noted that some of petitioners' claims, "even if not preempted, fail because [petitioners] have pointed to no evidence . . . upon which they could go to a jury." *Id.* at 52.

b. The Seventh Circuit affirmed. Drawing support from the reasoning of a majority of the Justices in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), the court determined that "[t]he phrase 'any requirement' in 21 U.S.C. § 360k(a) is broad enough to include at least some common law causes of action within the statute's

preemptive scope." Pet. App. 64a. The court rejected the petitioners' contention that Zyderm was not subject to any federal "requirement" within the meaning of the MDA preemption statute, pointing out that "the premarket approval process constitutes a 'specific requirement.'" *Id.* at 70a.

Turning to petitioners' particular claims, the court "agree[d] with several other circuits which have considered the issue that, with respect to a Class III device that has undergone the PMA process, [negligence and strict liability] claims are preempted because they undoubtedly would add requirements 'different from, or in addition to,' those set forth in the MDA." Pet. App. 73a. The court further determined that petitioners' additional claims of mislabeling and adulteration, fraud, and breach of warranty either also were preempted or, if not preempted, nonetheless had not been supported by sufficient evidence to withstand summary judgment. *Id.* at 75a-86a.

c. This Court then vacated and remanded for reconsideration in light of the intervening decision in *Medtronic*. On remand, the Seventh Circuit, after carefully analyzing *Medtronic*, once again affirmed.

The Seventh Circuit stressed at the outset "that the factual situation before the Court in *Medtronic* was substantially different from the one before us today." Pet. App. 7a. Whereas Collagen had not been permitted to market Zyderm until it had satisfied requirements relating to safety and effectiveness imposed pursuant to the PMA process, the FDA had allowed the device at issue in *Medtronic* to be marketed merely upon a showing that it was "substantially equivalent" to a device already on the market. This difference, the court determined, has critical significance under the MDA preemption statute.

In *Medtronic*, this Court held that a mere finding of substantial equivalence does not result in the imposition of specific federal requirements triggering preemption under 21 U.S.C. § 360k(a). In contrast, "the PMA process

imposed requirements that directly affected the safety and effectiveness of the product." Pet. App. 16a. Accordingly, the Seventh Circuit, agreeing with other courts that have considered the same issue following *Medtronic,* concluded that "the PMA process, as opposed to the 'substantially equivalent' process at issue in *Medtronic,* can constitute the sort of specific federal regulation of a product that can have preemptive effect." *Id.* at 17a, quoting *Papike v. Tambrands, Inc.,* 107 F.3d 737, 741 (9th Cir.), *cert. denied,* 118 S. Ct. 166 (1997).

The court then considered whether the MDA preemption statute reached state common law requirements that conflict with federal requirements imposed in connection with the PMA process. Closely analyzing the separate opinions in *Medtronic,* the court concluded that, in light of those opinions, "at least some state-based common law causes of action must be considered 'requirements' as that term is employed in the MDA." Pet. App. 15a. The proper test, the court believed, is "whether [a] final judgment [based upon the state law cause of action] would impose on the manufacturer a burden incompatible with the requirements imposed by the FDA." *Id.* at 18a. The court noted that subsequent to the decision in *Medtronic* other courts "have reached the same common-sense conclusion." *Id.* at 19a.

The court then "reevaluated each of [petitioners'] claims in light of our analysis of the Supreme Court's decision in *Medtronic.*" Pet. App. 21a. The court held that a strict liability

> claim is preempted by the PMA process for a Class III medical device. Approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling. The FDA's determination is specific to the product. A state court judgment premised on a contrary determination, as a finding of liability based on [petitioners'] strict liability claim necessarily would be, would constitute . . . a require-

> ment "different from, or in addition to," the standard required by federal authority.

Id. at 21a-22a. Similarly, the petitioners' "negligence claims must be considered preempted to the extent that they allege that Collagen was negligent despite its adherence to the standards required by the FDA in its PMA for this specific product." *Id.* at 22a.

The petitioners' claims of mislabeling, misbranding, and adulteration and of implied warranty, the court concluded, also were preempted to the extent that they sought to impose liability on Collagen "despite its conformity to the requirements of the PMA." Pet. App. 22a. On the other hand, the court recognized that claims of express warranty and allegations "that Collagen failed to meet the standards set forth in the PMA process . . . are not preempted." *Id.* However, petitioners had not supported such claims and allegations with sufficient evidence to withstand summary judgment. *Id.* at 22a-25a.

Finally, the court disposed of petitioners' claim that Collagen had made misrepresentations to the FDA during the PMA process (a claim that the FDA itself had implicitly rejected when it reviewed and reaffirmed its approval of Zyderm in 1992). The court earlier had explained that the MDA " 'does not permit such a searching state inquiry into the inner workings of FDA procedures.' " Pet. App. 80a, quoting *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995). This conclusion, the court believed, is not "altered by *Medtronic*." *Id.* at 23a.

ARGUMENT

1. The question of MDA preemption presented in this case is precisely the same as that recently presented to the Court in *Fiore v. Collagen Corp.*, 930 P.2d 477 (Ariz. Ct. App. 1996), *cert. denied*, —— S. Ct. ——, No. 96-1611, 1998 WL 6291 (Jan. 12, 1998), and is also the same as or closely related to those presented in

Kernats v. Smith Industries Medical Systems, Inc. 675 N.E.2d 634 (Ill. 1996), *cert. denied,* —— S. Ct. ——, No. 96-1405, 1997 WL 107232 (Jan. 12, 1998), *Martin v. Telectronics Pacing Sys., Inc.,* 105 F.3d 1090 (6th Cir. 1997), *cert. denied,* —— S. Ct. ——, No. 96-1749, 1998 WL 15431 (Jan. 20, 1998), and *Eddy v. Polymer Technology Corp.,* 692 A.2d 566 (Pa. 1997), *cert. denied,* —— S. Ct. ——, No. 97-26, 1998 WL 15432 (Jan. 20, 1998). The petitioners here offer no better or different reasons for granting their petition than were offered in those other cases. The Court denied the petitions in those cases and should deny the petition here as well.

2. There is no conflict warranting review. The court below, in a carefully reasoned opinion, held that the federal requirements imposed on the manufacturer of a medical device in connection with the PMA process give rise to federal preemption under 21 U.S.C. § 360k(a). In so holding, the court scrupulously followed this Court's teachings in *Medtronic* and, as the petitioners themselves concede, "[s]everal other courts . . . are in accord." Pet. 12. Indeed, after *Medtronic* no federal court of appeals or state supreme court has held to the contrary.

The cases upon which the petitioners rely in asserting a conflict, *see* Pet. 14-15, either were decided by trial courts or state intermediate appellate courts or did not concern medical devices that had been found safe and effective pursuant to the demanding PMA process at issue here. The two state supreme courts that actually have considered the matter agree, as the Seventh Circuit held in this case, that section 360k(a) preempts state common law requirements relating to the safety or effectiveness of a medical device that are in addition to or different from the requirements imposed by the FDA in connection with the granting of premarket approval. *Green v. Dolsky,* 685 A.2d 110 (Pa. 1996), *cert. denied,* 117 S. Ct. 1432 (1997); *Fry v. Allergan Medical Optics,* 695 A.2d 511 (R.I.), *cert. denied,* 118 S. Ct. 374 (1997). The Sixth

Circuit in *Martin* and the Ninth Circuit in *Papike v. Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir.), *cert. denied*, 118 S. Ct. 166 (1997), similarly have found preemption in closely related circumstances.

3. In view of this decisional uniformity, there is neither need nor occasion for the Court to revisit the issues so recently considered in *Medtronic*. The petitioners apparently would have the Court decide in the abstract whether "general state-law duties" are subject to preemption under section 360k(a). Pet. 12-14, 17-18. They point to the fact that the Tenth Circuit and the Supreme Court of Kentucky, in two cases having nothing to do with the PMA process, have held that in those very different circumstances section 360k(a) does not preempt broad common law causes of action. *See* Pet. 13-14, citing *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997), and *Niehoff v. Surgidev Corp.*, 950 S.W.2d 816 (Ky. 1997). But differences in legal and factual settings naturally can lead to differences in result.

As this Court recognized in *Medtronic*, whether section 360k(a) preempts state common law depends importantly on the context. A majority of the Court agreed that state common law duties may constitute requirements subject to preemption under the statute. *See Medtronic*, 116 S. Ct. at 2259-60 (Breyer, J., concurring), 2262-64 (O'Connor, J., concurring in part and dissenting in part). The Court held that the general state common law requirements invoked by the plaintiffs were not preempted, "but only after concluding that the federal labeling and manufacturing requirements at issue were not specific to [the medical device in question]." *Papike*, 107 F.3d at 742.

The broad federal requirements at issue in *Medtronic* "reflect[ed] important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation

which the statute or regulations were designed to protect from potentially contradictory state requirements." *Medtronic*, 116 S. Ct. at 2258. Consequently, the plaintiffs' common-law causes of action in that case did not interfere with the federal regulatory scheme and posed no "threat to federal requirements." *Id.* The Court took care to note, however, that in other contexts " 'general' state requirements [may be] pre-empted." *Id.* at 2257.

4. The decision below plainly is not, as the petitioners argue, "at odds with *Medtronic*." Pet. 16. This Court in *Medtronic* carefully distinguished between the abbreviated notification process at issue in that case and "the rigorous PMA review" satisfied by Zyderm in this case. *Medtronic*, 116 S. Ct. at 2247. In *Medtronic*, "the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the PMA process." *Id.* at 2254. Here, Zyderm successfully ran that gauntlet and was found to be safe and effective when manufactured and marketed in accordance with specifications approved by the FDA. 46 Fed. Reg. 46394 (1981).

Although the petitioners attempt to obscure the nature of the PMA process and to trivialize the requirements it imposes, that process of determining and assuring safety and effectiveness in fact lies at the heart of the regulatory program envisioned by Congress when it enacted the MDA. The stated purpose of the MDA is "to provide for the safety and effectiveness of medical devices intended for human use." *Medtronic*, 116 S. Ct. at 2245, quoting 90 Stat. 539. The PMA process is the formal regulatory mechanism by which this purpose is achieved. *Id.* at 2246-47. In turn, a central function of the MDA preemption statute is to insulate that process from state interference: section 360k(a) by its plain terms bars the states from interposing requirements conflicting with or departing from the federal requirements relating to safety

and effectiveness imposed in connection with the PMA process.

5. "During the PMA process, the federal government, it can truly be said, has 'weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case . . ., and implemented that conclusion via a specific mandate on [the] manufacturer[ ].'" Pet. App. 17a, quoting *Papike*, 107 F.3d at 741-42. The petitioners incorrectly argue that the PMA process "does not impose specific federal 'requirements' because the device's specifications originate with the manufacturer." Pet. 16. That is a non-sequitur. The origin of a federal rule or requirement is unimportant. A federal agency may, for example, solicit rule proposals from trade groups or individuals. But once the agency adopts a proposal, it becomes the federal standard regardless of origin. That is the case here.

In most (although not all) instances, manufacturing, labeling, and other specifications do indeed originate with the manufacturer. But once the FDA approves those specifications, which it does only after intensive scrutiny, they become specific and binding federal requirements. "A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that it is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80. The PMA approval order typically specifies, and did so in this case, that the manufacturer is required to adhere to the design, components, manufacturing methods, and labeling approved by the FDA in the course of the PMA process. These federal requirements are specific to the particular medical device; if the manufacturer fails to comply with these requirements, its "product is subject to withdrawal from the market." Pet. App. 17a. This is precisely "the sort of specific federal regulation of a product that can have preemptive effect" under section 360k(a). *Id.*

6. In attacking the Seventh Circuit's disposition of their claims of mislabeling and misbranding, Pet. 18, the petitioners misread the opinion below. The court agreed with the petitioners that section 360k(a) does not preempt common law claims grounded in allegations that a manufacturer violated federal requirements. *See* Pet. App. 22a. The court simply held, after reviewing the petitioners' summary judgment filings, that they had not asserted such claims against Collagen. *Id.* at 23a; *see also id.* at 75a-78a.

7. Finally, the petitioners miss the point in contending, Pet. 18-20, that they should be entitled to assert a state-law cause of action predicated on the allegation (which the FDA itself implicitly rejected upon reexamination; *see* Pet. App. 3a) that Collagen made misrepresentations during the PMA process. The thrust of such a cause of action is that the FDA's approval of a medical device should be disregarded, with state common law standards being substituted for the federal requirements that accompanied such approval. It is difficult to imagine a clearer case for preemption:

> "Surely, where the FDA was authorized to render the expert decision on [Zyderm's] use and labeling, it, and not some jury or judge, is best suited to determine the factual issues and what their effect would have been on its original conclusions. Further, if the court erred, and incorrectly posited the effect on the FDA's use and labeling decision, this would impose a state requirement 'which is different from, or in addition to, any requirement applicable . . . to the device.'"

Pet. App. 80a, quoting *King v. Collagen Corp.*, 983 F.2d 1130, 1140 (1st Cir.) (Aldrich and Campbell, JJ., concurring), *cert. denied*, 114 S. Ct. 84 (1993). *See also Michael*, 46 F.3d at 1329.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

JOE W. REDDEN, JR.
Counsel of Record
KEITH A. JONES
BECK, REDDEN & SECREST
1221 McKinney Street
Suite 4500
Houston, TX 77010-2010
(713) 951-3700
Attorneys for Respondent